What is claimed is:

1. A therapeutic agent for treating HIV infection, comprising an immunostimulatory recombinant Tat protein.

2. The therapeutic agent according to claim 1, wherein the Tat protein consists of amino acids 1-72 of wild-type Tat or peptide derivatives thereof.

3. The therapeutic agent according to claim 1, wherein the Tat protein consists of amino acids 1-86 of wild-type Tat or peptide derivatives thereof.

4. The therapeutic agent according to claim 1, wherein the Tat protein consists of mTat I-86, wherein amino acid 22 is Gly-22 or other mutations in the protein.

5. The therapeutic agent according to claim 1, further comprising one or more adjuvants.

6. The therapeutic agent according to claim 5, wherein the adjuvant is selected from the group consisting of alum, HPC and lipid A.

7. The therapeutic agent according to claim 1, in particulate form.

8. The therapeutic agent according to claim 1, wherein the Tat protein is obtained by a process comprising the steps of:

biosynthesizing Tat in a bacterial cell culture;
producing a crude isolate of Tat;
removing bacterial RNA from Tat; and
isolating Tat from endotoxin.

9. The therapeutic agent according to claim 8, wherein the step for biosynthesizing a crude isolate of biosynthesizing Tat in a bacterial cell culture comprises introducing DNA coding for a naturally biotinylated fusion protein of Tat into a bacterial cell culture, isolating from the bacterial cell culture a naturally

biotinylated fusion protein of Tat by affinity chromatography on an avidin resin, and cleaving Tat from the fusion protein with factor Xa.

10. The therapeutic agent according to claim 9, wherein the step for producing a crude isolate of Tat comprises eluting cleaved Tat from the avidin resin.

11. The therapeutic agent according to claim 8, wherein the step for removing bacterial RNA from Tat comprises digesting the bacterial RNA in the presence of RNAse.

12. The therapeutic agent according to claim 11, wherein the step for isolating Tat from endotoxin comprises exposing Tat to a polymixin column to remove endotoxin.

13. A method to induce humoral and cellular responses using an immunostimulatory recombinant Tat protein that is autonomously internalized by cells.

14. The method according to claim 13, wherein the Tat protein consists of amino acids 1-72 of wild-type Tat or peptide derivatives thereof.

15. The method according to claim 13, wherein the Tat protein consists of amino acids 1-86 of wild-type Tat or peptide derivatives thereof.

16. The method according to claim 13, wherein the Tat protein consists of mTat I-86, wherein amino acid 22 is Gly-22 or other mutations in the proteins.

17. The method according to claim 13, wherein the Tat protein is obtained by a process comprising the steps of:

biosynthesizing Tat in a bacterial cell culture;
producing a crude isolate of Tat;
removing bacterial RNA from Tat; and
isolating Tat from endotoxin.

18. The method according to claim 17, wherein the step for biosynthesizing a crude isolate of biosynthesizing Tat in a bacterial cell culture comprises introducing DNA coding for a naturally biotinylated fusion protein of Tat into a bacterial cell culture, isolating from the bacterial cell culture a naturally biotinylated fusion protein of Tat by affinity chromatography on an avidin resin, and cleaving Tat from the fusion protein with factor Xa.

19. The method according to claim 17, wherein the step for producing a crude isolate of Tat comprises eluting cleaved Tat from the avidin resin.

20. The method according to claim 17, wherein the step for removing bacterial RNA from Tat comprises digesting the bacterial RNA in the presence of RNAse.

21. The method according to claim 17, wherein the step for isolating Tat from endotoxin comprises exposing Tat to a polymixin column to remove endotoxin.

22. A process for producing a Tat protein, said process comprising the steps of:
biosynthesizing Tat in a bacterial cell culture;
producing a crude isolate of Tat;
removing bacterial RNA from Tat; and
isolating Tat from endotoxin.

23. The process according to claim 22, wherein the step for biosynthesizing a crude isolate of biosynthesizing Tat in a bacterial cell culture comprises introducing DNA coding for a naturally biotinylated fusion protein of Tat into a bacterial cell culture, isolating from the bacterial cell culture a naturally biotinylated fusion protein of Tat by affinity chromatography on an avidin resin, and cleaving Tat from the fusion protein with factor Xa.

24. The process according to claim 22, wherein the step for producing a crude isolate of Tat comprises eluting cleaved Tat from the avidin resin.

25. The process according to claim 22, wherein the step for removing bacterial RNA from Tat comprises digesting the bacterial RNA in the presence of RNAse.

26. The process according to claim 22, wherein the step for isolating Tat from cytotoxin comprises exposing Tat to a polymixin column to remove cytotoxin.

27. A process of making Tat that is non-denatured and free of Bacterial RNA and endotoxin, the process comprising the steps of:

subcloning Tat into a bacterial vector as a N-terminally biotinylated fusion protein;

transforming a bacterial host with the cloned bacterial vector to express the fusion protein in the bacterial host;

isolating the fusion protein on an avidin column;

cleaving Tat from the fusion protein;

digesting RNA from Tat in the presence of RNAse; and

removing endotoxin from Tat;

the foregoing steps producing said non-denatured, bacterial RNA- and endotoxin- free Tat.

28. Non-denatured, bacterial RNA-free and endotoxin-free Tat.

29. The use of Tat for inducing an immune response.

30. A method of treating HIV infection comprising administering to a subject in need thereof, an immune-response inducing effective amount of the therapeutic agent of claim 1.

31. The method of claim 30 wherein the therapeutic agent further comprises an adjuvant.

32. The method according to claim 31, wherein the adjuvant is selected from the group consisting of alum, HPC and lipid A.

33. A Tat-absorbed nanoparticle.

34. The nanoparticle according to claim 33, wherein the Tat consists of amino acids 1-72 of wild-type Tat or peptide derivatives thereof.

35. The nanoparticle according to claim 33, wherein the Tat consists of amino acids 1-86 of wild-type Tat or peptide derivatives thereof.

36. The nanoparticle according to claim 33, wherein the Tat consists of mTat 1-86, wherein amino acid 22 is Gly-22 or other mutations in the protein.

37. The Tat-absorbed nanoparticle according to claim 33 obtained by a process comprising the steps of:

producing a Tat protein according to the process comprising:

biosynthesizing Tat in a bacterial cell culture;

producing a crude isolate of Tat;

removing bacterial RNA from Tat; and

isolating Tat from endotoxin;

preparing purified anionic nanoparticles from microemulsion precursors; and

mixing the purified nanoparticles with the Tat protein.

38. The Tat-adsorbed nanoparticle according to claim 37, wherein the step for biosynthesizing a crude isolate of biosynthesizing Tat in a bacterial cell culture comprises introducing DNA coding for a naturally biotinylated fusion protein of Tat into a bacterial cell culture, isolating from the bacterial cell culture a naturally biotinylated fusion protein of Tat by affinity chromatography on an avidin resin, and cleaving Tat from the fusion protein with factor Xa.

39. The Tat-adsorbed nanoparticle according to claim 37, wherein the step for producing a crude isolate of Tat comprises eluting cleaved Tat from the avidin resin.

40. The Tat-adsorbed nanoparticle according to claim 37, wherein the step for removing bacterial RNA from Tat comprises digesting the bacterial RNA in the presence of RNAse.

41. The Tat-adsorbed nanoparticle according to claim 37, wherein the step for isolating Tat from endotoxin comprises exposing Tat to a polymixin column to remove endotoxin.

42. The Tat-adsorbed nanoparticle according to claim 37, further comprising incubating the mixture of purified nanoparticles and Tat with phosphate-buffered saline, fetal bovine serum in normal saline, or lactose.

43. A process for producing a Tat-adsorbed nanoparticle comprising the steps of:
producing a Tat protein according to the process of claim 22;
preparing purified anionic nanoparticles from microemulsion precursors; and
mixing the purified nanoparticles with Tat.

44. The process according to claim 43, wherein the step for biosynthesizing a crude isolate of biosynthesizing Tat in a bacterial cell culture comprises introducing DNA coding for a naturally biotinylated fusion protein of Tat into a bacterial cell culture, isolating from the bacterial cell culture a naturally biotinylated fusion protein of Tat by affinity chromatography on an avidin resin, and cleaving Tat from the fusion protein with factor Xa.

45. The process according to claim 43, wherein the step for producing a crude isolate of Tat comprises eluting cleaved Tat from the avidin resin.

46. The process according to claim 43, wherein the step for removing bacterial RNA from Tat comprises digesting the bacterial RNA in the presence of RNAse.

47. The process according to claim 43, wherein the step for isolating Tat from endotoxin comprises exposing Tat to a polymixin column to remove endotoxin.

48. The process according to claim 43, further comprising incubating the mixture of purified nanoparticles and Tat with phosphate-buffered saline, fetal bovine serum in normal saline, or lactose.

49. A method to induce humoral and cellular responses comprising administering to a subject in need thereof, an effective amount of a Tat-adsorbed nanoparticle.

50. The method of claim 49, wherein the cellular response is a Th1-type response.

51. A method of treating HIV infection comprising administering to a subject in need thereof, an immune-response inducing effective amount of a Tat-adsorbed nanoparticle.

52. A Tat-adsorbed nanoparticle delivery system for the delivery of protein antigens comprising the Tat-adsorbed nanoparticle according to claim 33.